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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,683	01/22/2002	Lloyd J. Old	L0461/7125	5148

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,683	OLD ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,14,15,29,31 and 74-78* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12, 14, 15, 29, 31, and 74-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on 08 April 2005 is acknowledged. Claims 12, 14, 15, 29, 31, and 74-78 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office action contains new grounds of rejection

Claim Objections, Withdrawn

The objection of claims 14, 29, and 74-78 are withdrawn in view of the amendment.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 12 and 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102, Maintained

Claims 12, 14, 15, and 74-77 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. 5935578 A (Aug. 10, 1999).

Claims 12, 14, 15, and 74-77 are interpreted as drawn to a pharmaceutical composition comprising a polypeptide encoded by SEQ ID NO:19, and pharmaceutically acceptable carrier for intended use of generating T cell medicated response along with an HLA molecule or one or more of MHC molecules presented on the surface of non-testis cells (claim 74), wherein an adjuvant is further comprised in claim 77.

Applicant argues that the claims are amended to reflect the claimed composition contain plurality of cancer-testis antigen polypeptides or fragments. US Pat. 5935578 does not teach the protein identical to the instant SEQ ID NO: 19 protein is associated in cancer in any way, nor does the patent teach the production of combinations of cancer-testis antigen polypeptides, or fragments thereof, or fusion proteins containing these polypeptides.

These arguments have been fully considered but found unpersuasive. As for applicant's statement that the prior art of record that odes not teach the protein identical to the SEQ ID NO: 19 being a cancer antigen, the Office is in agreement with applicant's assessment as the previous Office action indicates. However, the instantly claimed invention is a composition whose main ingredient is identical to the protein disclosed in the prior art of record. As the previously provided Exhibit A (sequence alignment of instant SEQ ID NO:19 protein against SEQ ID NO:8 of US Pat. 5935578 A) demonstrates, SEQ ID NO:8 of the patent matches 100 % to instant SEQ ID NO: 19 encoded by instant SEQ ID NO: 18. Therefore, SEQ ID NO: 8 of the prior art must possess (inherently posses) the same function (i.e. being a cancer antigen) since the structure of the claimed invention and the structure of the prior art of record are identical structures.

As for the argument that the prior art of record does not teach he production of combinations of cancer-testis antigen polypeptides, or fragments thereof, or fusion proteins containing these polypeptides, the Office could not understand what this argument is about. If the argument is about the claimed pharmaceutical composition

having more than one active ingredient, the amendment filed on 08 April 2005 is attempting to change the invention during the mid-prosecution. This attempt is not allowed and the amendment would be a non-response amendment. Note the Restriction Requirement mailed on 10/06/2004, and applicant's subsequence election. In these correspondences, both the Office and applicant agreed that the elected invention is drawn to composition comprising one active ingredient, which is SEQ ID NO: 19. The other interpretation of applicant's argument and the scope of the amended claims could be that the limitation "polypeptides" in line 2 of the amended base claim 12 could be plurality (multiple numbers) of a single protein or fragments thereof. If that is the case, then US Pat. 5935578 A at column 2, lines 57-66 teaches composition comprising at least one epitope from the newly discovered human protein in a "pharmaceutically acceptable carrier". US Pat. 5935578 also teaches at Example 3, column 12, lines 24-27 a vaccine preparation, i.e. "The affinity-purified PH30 beta, in 0.375 ml phosphate-buffered saline (PBS) containing 3 mM octyglucoside (OG) is emulsified with 0.375 ml complete Freund's adjuvant (CFA)." Thus, US Pat. 5935578 A teaches a plurality of proteins in a pharmaceutically acceptable carrier and adjuvant.

Although US Pat. 5935578 does not teach whether the human PH30 beta chain sperm protein (SEQ ID NO: 8) could form a complexes of HLA or any other MHC molecules presented on the surface of non-testis cells when administered to a human subject, it is the Office position that the protein of the prior art meets that limitations of the instant claims because the structure of the proteins are the same and must possess the same function if they are identical structures.

Any other rejection not repeated here is withdrawn.

Claim Rejections - 35 USC § 103

Claims 74, 77, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. 5,935,578 A (Aug. 10, 1999) in view of US 5,961,979 A (October 5, 1999).

Claims 74, 77, and 78 are interpreted as drawn to a composition comprising SEQ ID NO:19 and saponins as an adjuvant.

Applicant argues that the primary reference (i.e. US Pat. 5,935,578 A) does not provide the elements of the invention as amended because the primary reference does not teach or suggest combinations of a plurality of peptides that are fragments of cancer-testis antigen polypeptides. The secondary reference (US 5,961,979 A) while teaching the adjuvant, does not supplement the elements missing from the primary reference.

These arguments have been fully considered but found unpersuasive.

US Pat. 5935578 A teaches a protein identical to instant SEQ ID NO:19, and adjuvant. Note the 102 (b) rejection above for further details.

US Pat. 5935578 A does not specifically teach those adjuvant species listed in the instant claims 78.

However, US 5961979 A teaches at column 23 line 24 that saponins are well known adjuvant commonly used in the art to stimulate immune response.

Therefore, it would have been obvious and motivated to use saponins as an adjuvant with reasonable expectation of success for non-specific immunostimulator effect since the art knows how to make and use saponins as an adjuvant in a vaccine.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 112

Claims 29, and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This written description rejection is made because claims 29, and 31 are interpreted as drawn to a composition comprising a genus of fusion proteins constructed by fusing at least two different human cancer-testis antigens, wherein the first one of at least two different human cancer-testis antigens comprise a polypeptide sequence encoded by SEQ ID NO: 18, and the second one of at least two different human cancer-testis antigens comprises a genus of human cancer-testis antigens.

The applicable standard for the written description requirement can be found: MPEP 2163; University of California v. Eli Lilly, 43 USPQ2d 1398 at 1407; PTO Written Description Guidelines; Enzo Biochem Inc. v. Gen-Prove Inc., 63 USPQ2d 1609; Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111; and University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 (CA FC 2004).

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In this case, the only factor present for the second one of "at least two different polypeptides" required for making for the claimed genus of fusion proteins is the limitation "human cancer-testis antigens". Consulting the specification, especially at abstract, where "Cancer-testis (CT) antigens" are defined as "genes that are expressed in cancer and testis tissues (but not other normal tissues)", the limitation "human cancer-testis antigens" appears to be a random laboratory designated name by the instant applicant. The limitation is not an art-recognized term. In other words, one of skill in the art would not know what kind of chemical structure(s) the instantly claimed polypeptide by "human cancer-testis antigens" would have. Based on the definition of "human cancer-test (CT) antigen", one of skill would not know what kind of function the claimed genus of the polypeptides would have, either, because a gene being expressed in cancer and testis tissues (but not other normal tissues) is not a function of a polypeptide being claimed. Rather, it is a reflection of a promoter activity of a gene in response to changing conditions of a human body, i.e. development of cancer or based on the differences in promoter and/or other gene expression machinery differences in a specific tissue (for example, testis tissue as compared to other normal tissue). In

summary, there is not even identification of any structure or function for the second part of the claimed genus of the fusion proteins. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642